

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

**IN RE: JOHNSON & JOHNSON TALCUM
POWER PRODUCTS MARKETING,
SALES PRACTICES, AND PRODUCTS
LIABILITY LITIGATION**

MDL No. 16-2738 (MAS) (RLS)

***THIS DOCUMENT RELATES TO ALL
CASES***

**DEFENDANTS JOHNSON & JOHNSON AND LLT MANAGEMENT
LLC'S BRIEF IN OPPOSITION TO PLAINTIFFS' MOTION TO
EXCLUDE THE OPINIONS OF DR. KATHLEEN SUTCLIFFE**

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INTRODUCTION

Plaintiffs' brief drips with sarcasm and disdain for the four decades of work Dr. Kathleen Sutcliffe has undertaken as a leading scholar in the field of organization science, theory, and behavior at universities such as Johns Hopkins and Michigan. Plaintiffs' primary complaint appears to be that because this litigation involves certain technical aspects, an organizational scientist is in over her head. That position would come as a surprise to the National Academy of Sciences, who appointed Dr. Sutcliffe to the Committee on Emerging Trends in Aviation Safety not because she is an expert in the highly technical field of aviation—she most definitely is not—but rather precisely for her organizational science expertise.

Dr. Kathleen Sutcliffe's focus over her career has been on how organizations process information and make decisions under uncertainty. Given her expertise, in response to Plaintiffs' allegations that J&J and its affiliates (collectively "J&J") have known for decades that its talcum powder products pose risks to consumers and that J&J ignored and covered up those health risks, Dr. Sutcliffe was asked to assess J&J's knowledge as an organization regarding allegations that its talc products are unsafe. She analyzed when it had relevant knowledge and what actions it took to get it—as well as whether its actions in response to that knowledge were consistent with an organizational commitment to the wellbeing of consumers. In sum, Dr. Sutcliffe is offering an opinion on J&J's corporate knowledge and corporate actions. And she

has the precise qualifications necessary to offer that opinion, having conducted decades of research and assessments of organizations across a variety of industries.

Plaintiffs denigrate Dr. Sutcliffe's 40-year career and a well-established body of research and publications in organizational science to try to persuade this Court that the study of organization theory and behavior is nothing but junk science. They scoff at terms like "sensemaking" and "disruptive ambiguity" as "gauzy" phrases devoid of meaning, and deem Dr. Sutcliffe's methodology to be "made up." But one read of Dr. Sutcliffe's thoroughly supported report and those arguments fall flat. Dr. Sutcliffe employed a detailed qualitative methodology and conceptual framework that are thoroughly explained in her report. Many courts have upheld qualitative methodologies that, like Dr. Sutcliffe's, are well-grounded in academic literature.

In an attempt to challenge both the reliability of her methods and the fit of her opinions to this case, Plaintiffs claim that Dr. Sutcliffe limited her analysis to the 1970s and ignored evidence of a link between talc and ovarian cancer. Plaintiffs misrepresent Dr. Sutcliffe's deposition testimony and report—which make clear that she analyzed J&J's knowledge and behavior around the safety of its products starting with an initially disruptive period in 1971 through the discontinuation of Johnson's Baby Powder in 2023.

Plaintiffs' attempt to exclude "opinions" by Dr. Sutcliffe about asbestos testing is likewise easily disposed of. Dr. Sutcliffe has made clear that she is not

offering any opinions on asbestos testing, mineralogy, toxicology, or epidemiology. Dr. Sutcliffe is an organizational scientist who is opining on what J&J knew and when, and on J&J’s organizational behavior. Her opinions regarding *J&J’s response* to allegations and testing around the presence of asbestos in talc should not be stricken.

Dr. Sutcliffe’s opinions squarely “fit” this case, as they directly challenge Plaintiffs’ allegations regarding J&J’s knowledge, motivations, and actions. The Court should deny Plaintiffs’ motion to exclude her opinions.

ARGUMENT

I. Dr. Sutcliffe is highly qualified to opine on J&J’s corporate knowledge and actions with respect to the safety of its talc products.

Under Rule 702, an expert is “qualified to render an opinion when he or she ‘possesses specialized expertise.’” *In re Human Tissue Prods. Liab. Litig.*, 582 F. Supp. 2d 644, 655 (D.N.J. 2008) (quoting *Pineda v. Ford Motor Corp.*, 520 F.3d 237, 244 (3d Cir. 2008)). The bar to survive a challenge to an expert’s qualifications is not a high one. This Circuit has “eschewed imposing overly rigorous requirements of expertise.” *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 741 (3d Cir. 1994). The Court need only determine “whether the proffered expert has minimal qualifications, either through experience or education, in a field that is relevant to a subject which will assist the trier of fact.” *Poust v. Huntleigh Healthcare*, 998 F. Supp. 478, 491 (D.N.J. 1998); *see also In re Paoli*, 35 F.3d at 741 (describing Rule 702’s “liberal

policy of admissibility” when it comes to experts’ qualifications); *see also Pineda*, 520 F.3d at 2444-45. Dr. Sutcliffe hurdles this bar easily.

Dr. Sutcliffe is an expert in organization science, behavior, and theory who studies “organizational adaptability, reliability, and resilience.”¹ In other words, she studies how companies process and respond to information in order to determine what they could have done better in a given situation and how they can anticipate and prevent future issues.² During the course of her career, Dr. Sutcliffe has studied, among other things, how organizations process and make sense of ambiguous information and how they make decisions under uncertainty.³ She is thus well qualified to opine on the knowledge that J&J possessed around the safety of talc over time and the actions it took in response to that knowledge.

Dr. Sutcliffe has been studying and teaching organization science for forty years. She holds a Ph.D. in Organization Theory and Behavior from the University of Texas at Austin. Currently a professor at Johns Hopkins University and formerly at the Universities of Michigan and Minnesota, she teaches graduate and undergraduate courses on organizational behavior and theory, leading and managing

¹ (Expert Rep. of Dr. Kathleen M. Sutcliffe, Ph.D., April 12, 2024 (“Rep.”) (attached as Ex. 1 to Cert. of John Ewald (“Ewald Cert”)) ¶ 2; Dep. of Dr. Kathleen M. Sutcliffe, Ph.D., May 28, 2024 (“Sutcliffe Dep.”) (attached as Ex. 2 to Ewald Cert.) 14:18-22.)

² (*See* Rep. ¶ 10.)

³ (*Id.* ¶ 2.)

change, and organizational learning.⁴ She is a member of several professional organizations, including the Academy of Management, the European Group for Organizational Studies, the Institute for Operations Research and the Management Sciences, and the Strategic Management Society.⁵ She is widely published in a range of academic and practice-related journals and has co-authored/co-edited eight books on organizational responses to risks.⁶ For example, Dr. Sutcliffe authored a book chapter regarding her organizational assessment of Toyota's culture in connection with its inability to make sense of and respond appropriately to unintended acceleration issues and also provided testimony for plaintiffs in litigation on that topic.⁷ Her research and consulting work has spanned many industries and subject matters.⁸

In this case, after reviewing an extensive set of materials, applying an established research methodology and highly cited framework, and drawing upon decades of organization science research, Dr. Sutcliffe reached the conclusion that

⁴ (Rep. ¶ 1; *id.* App. A at A-1, A-28-29.)

⁵ (*Id.*; *id.* App. A at A-33)

⁶ (*Id.* ¶ 4; *id.* Rep. App. A.)

⁷ (Rep. App. at A-2, Weick, K.E. & Sutcliffe, K.M., MANAGING THE UNEXPECTED: SUSTAINABLE PERFORMANCE IN A COMPLEX WORLD (3d. ed. 2015), Ch. 8: *Organizational Culture and Reliability.*) See *In re: Toyota Motor Corp. Unintended Acceleration Marketing, Sales Pracs., and Prods. Liab. Litig.*, No. 8:10ML-2151-JVS (FMOx) (C.D. Cal. 2010)).

⁸ (See Rep. ¶¶ 4-5; see generally App. A.)

“J&J actively pursued knowledge regarding the potential health risks associated with its baby powder, consistent with the incentives, motivations, and actions of an organization committed to the wellbeing of consumers.”⁹ She opines that allegations that J&J knew or hid information about the alleged health risks associated with its talc products are inconsistent with J&J’s behaviors, actions, decisions, and organizational priorities.¹⁰ Dr. Sutcliffe has precisely the right qualifications to offer these opinions—which are confined to J&J’s organizational knowledge and behavior.

Dr. Sutcliffe made clear in her report and her testimony what kind of expertise she does **not** have and what kind of opinions she is **not** offering. She is **not** an epidemiologist, a toxicologist, a mineralogist, a microscopist, or a geologist.¹¹ She is **not** an expert in mining, an expert in testing talc, or a regulatory expert.¹² She readily disclaims any special knowledge in those fields and has stated clearly that she is not offering any opinions outside the field of organization science.¹³ Dr. Sutcliffe is not offering any opinion at all regarding the safety of talc.

⁹ (*Id.* ¶ 14.)

¹⁰ (*Id.* ¶¶ 16-17.)

¹¹ (Sutcliffe Dep. 49:12-50:22, 53:3-54:11, 159:1-7.)

¹² (*Id.* 49:12-50:22, 55:4-56:16, 159:18-22.)

¹³ (Rep. ¶ 9 n.3; *id.* ¶ 19 (“I do not offer opinions on any issues discussed by plaintiff lawyers or experts that lie outside of my expertise in organizational science.”).)

Unlike Plaintiffs' expert Dr. David Kessler—who also is not a mineralogist, a microscopist, or a geologist—Dr. Sutcliffe is **not** opining on the presence or lack thereof of asbestos in talc products.¹⁴ She has made clear that she is **not** offering opinions on “testing or sensitivity, reliability or validity of the testing.”¹⁵ To the extent that her report describes testing, it is in connection with her assessment of J&J’s knowledge and reactions to the state of the industry and scientific literature over time.

Dr. Sutcliffe need not possess expertise in mineralogy, toxicology, or testing to offer the opinions she does on J&J’s knowledge and behavior as a company. There are many real-world examples outside of the litigation context that demonstrate how her expertise in organization science is not industry- or subject matter-specific. Dr. Sutcliffe has applied this expertise to many other industries and contexts, including

¹⁴ (Dep. 137:6-12 (“I am not opining on asbestos either.”)).

¹⁵ (Sutcliffe Dep. 391:9-18; *see also id.* 50:19-22 (“I’m not an expert on testing, and I’m not opining in this - - in this matter.”), 396:4-10 (“I am not opining on” the difference between something being “asbestos-free” or having “no detectable asbestos”).)

but not limited to nuclear energy and defense,¹⁶ firefighting,¹⁷ and healthcare.¹⁸ For example, the Transportation Research Board of the National Academies of Science, Engineering and Medicine (“The National Academies”) invited Dr. Sutcliffe to sit on the Committee on Emerging Trends in Aviation Safety.¹⁹ The National Academies recognize that she need not be an expert in aeronautics or aviation safety to provide insight regarding governmental and organizational responses to operational data and investigations of accidents and incidents. She was included on the committee because of her expertise in how organizations process information, set priorities, and react accordingly.²⁰

¹⁶ (Rep. App. A at A-18, Sutcliffe, K.M., Leadership and safety culture, Invited expert testimony at the Defense Nuclear Facilities Safety Board Safety Culture Public Meeting and Hearing (Aug. 27, 2014).)

¹⁷ (Rep. ¶¶ 3-5; *id.* App. A at A-4, A-6, A-10, A-18, A-20, and A-33, including, e.g., Barton, M., Sutcliffe, K.M., Vogus, T.J., & Dewitt, T., *Performing under uncertainty: Contextualized engagement in wildland firefighting*, 23(2) J. OF CONTINGENCIES AND CRISIS MGMT. 74-89 (2015); Black, A.E., Sutcliffe, K.M., Barton, M.A., Dether, D., *Assessing high reliability practices in the wildland fire community*, 68(2) FIRE MGMT. TODAY 45-48 (2008).)

¹⁸ (Rep. ¶¶ 3, 5; *id.* App. A at A-1, A-12, including, e.g., WEARS, R. & SUTCLIFFE, K. M., STILL NOT SAFE: PATIENT SAFETY AND THE MIDDLE MANAGING OF AMERICAN MEDICINE (2020).)

¹⁹ (Rep. ¶ 1; *id.* App. A at A-31.) See *Emerging Trends in Aviation Safety, About*, NAT'L ACADS. OF SCI., ENG'G, AND MED., <https://www.nationalacademies.org/our-work/emerging-trends-in-aviation-safety> (accessed Aug. 13, 2024).

²⁰ See *Emerging Trends in Aviation Safety, Committee, Kathleen M. Sutcliffe*, NAT'L ACADS. OF SCI., ENG'G, AND MED., <https://www.nationalacademies.org/our-work/emerging-trends-in-aviation-safety#sectionCommittee> (accessed Aug. 13,

Plaintiffs argue that “[i]n a surgery malpractice case, a party may not call a non-medical expert on the ‘sensemaking’ of the defendant in responding to the ‘disruptive ambiguity’ during the surgery.” Br. at 12. That misguided analogy reflects a fundamental misunderstanding of what sensemaking is and the opinions that Dr. Sutcliffe is offering. An organizational science expert would not opine on the medical aspects of surgery. But she *could* offer—and in fact Dr. Sutcliffe *has published* on—her scientific opinions about the “systemic/organizational origins of medical mistakes” in the healthcare context.²¹ In fact, she recently co-authored a book on that subject.²²

2024) (“Her research program has been devoted to investigating how organizations and their members cope with uncertainty and how organizations can be designed to be more reliable and resilient. She has investigated organizational safety, high reliability, and resilience practices in oil and gas exploration and production, chemical processing, steel production, wildland firefighting, and in healthcare.”). Dr. Sutcliffe and the Committee recently published their second report on ensuring safety during transformative changes. (*See Emerging Trends in Aviation Safety, Emerging Hazards in Commercial Aviation—Report 2: Ensuring Safety During Transformative Changes*, 57 NAT’L ACADS. OF SCI., ENG’G, AND MED. (2024) (attached as Ex. 3 to Ewald Cert.).)

²¹ (Rep. ¶¶ 3, 4 (describing her assessment of the organizational and cultural factors resulting in excessive rates of pediatric cardiac deaths at the Bristol Royal Infirmary in the UK).)

²² (*See, e.g.*, Rep. App. A-1, WEARS, R. & SUTCLIFFE, K. M., STILL NOT SAFE: PATIENT SAFETY AND THE MIDDLE MANAGING OF AMERICAN MEDICINE (2020). *See also, e.g.*, *id.* at A-7, Weick, K.E., & Sutcliffe, K. M., *Hospitals as cultures of entrapment*, 45(2) CAL. MGMT. REV. 73-84 (2003) (nominated by the editorial board as one of three best papers of 2003) and *id.* at A-11, ROSENTHAL, M. M., & SUTCLIFFE, K. M., MEDICAL ERROR: WHAT DO WE KNOW? WHAT DO WE DO? (2002).)

Similarly, here Dr. Sutcliffe is not opining on the scientific aspects of talc safety. Rather, Dr. Sutcliffe studies organizations and their knowledge, processes, and behaviors—and that is precisely what she did here. Her opinion assesses what information J&J knew over the past several decades and how it responded to that information—an opinion she is highly qualified to make.

II. Dr. Sutcliffe’s qualitative methodology used to assess J&J’s organizational knowledge and behavior is reliable.

Plaintiffs scoff at Dr. Sutcliffe’s use of terms like “sensemaking” and “disruptive ambiguity”—terms used regularly in the field of organization science—but which they characterize as “gauzy” and “gobbledygook.” Br. at 3-4, 30. Plaintiffs’ (perhaps deliberate) failure to understand Dr. Sutcliffe’s methodology and conceptual framework is not reason for this Court to reject it as unreliable. Plaintiffs challenge her methodology as “qualitative” and therefore untestable and involving “cherry-picking evidence” that supports J&J’s litigation position while “ignoring” evidence that is harmful to J&J—including all evidence of potential safety issues with talc after the 1970s. Br. at 1-2, 14. None of Plaintiffs’ arguments hold water.

A. Dr. Sutcliffe’s qualitative assessment employed a widely cited framework supported by decades of research in organization science and established qualitative methods.

An expert may rely on qualitative methods used for social sciences. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152, 119 S.Ct. 1167, 143 L.Ed.2d 238 (1999) (“The objective of [Daubert’s gatekeeping] requirement is . . . to make certain

that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.”). In reaching her opinions, Dr. Sutcliffe drew on the methodologies and frameworks that researchers employ to assess organizations in the field of organizational theory and behavior, including the seminal works of Matthew B. Miles and A. Michael Huberman regarding qualitative analysis, and of Karl E. Weick regarding sensemaking.²³ Dr. Sutcliffe’s report provides a robust description of the methods, research design, and best practices she used to ensure that her qualitative assessment was reliable.

In order to understand what J&J knew about the safety of talc and when, Dr. Sutcliffe undertook a “retrospective review of the available evidence arrayed against a framework designed to assess the contemporaneous incentives, motivations, and actions of an organization.”²⁴ She employed a qualitative methodology and the widely cited conceptual framework of “sensemaking.”²⁵ Sensemaking is an “established framework for evaluating how new information enters an organization, how the organization interprets that information, and how the organization then

²³ MILES, MATTHEW B. AND A. MICHAEL HUBERMAN, QUALITATIVE DATA ANALYSIS (2nd ed. 1994) (“Miles and Huberman”) (excerpt attached as Ex. 4 to Ewald Cert.); WEICK, KARL E., “SENSEMAKING IN ORGANIZATIONS,” FOUNDATIONS FOR ORGANIZATIONAL SCIENCE (1995).

²⁴ (Rep. ¶ 42.)

²⁵ (See Sutcliffe Dep. 19:19-20:16, 23:20-24.)

chooses to act upon the information.”²⁶ As Dr. Sutcliffe outlined in her report, sensemaking is a framework supported by decades of research.²⁷

To assess J&J’s development of institutionalized knowledge, Dr. Sutcliffe used analytical tools such as case studies, textual analysis, and research that were “particularly appropriate for investigating complex processes as they unfold over time,” including “how J&J, industry regulators, scientists, and the press acquired new knowledge to inform their actions and develop new frameworks for understanding the potential health risks associated with cosmetic talc use.”²⁸ Her report details her research design, which included developing a set of intellectual “bins” (i.e., categories) of information to assess how J&J built on previous

²⁶ (Rep. ¶ 42; *see also* Sutcliffe Dep. 98:4-99:8 (“Sensemaking is a way to understand the process of how entities . . . develop their institutionalized knowledge.”).)

²⁷ (See, e.g., ¶ 42 nn.19-21 (listing numerous journal citations regarding sensemaking, including a review of 147 articles that have applied a sensemaking framework within the context of an organizational study); Maitlis, Sally and Marlys Christianson, *Sensemaking in Organizations: Taking Stock and Moving Forward*, 8(1) THE ACAD. OF MGMT. 58, 94 (2014) (attached as Ex. 5 to Ewald Cert.) (“Sensemaking—the process through which individuals work to understand novel, unexpected, or confusing events—has become a critically important topic in the study of organizations.”). “Since its first clear conceptualization (Weick, 1995), sensemaking has been studied by several scholars in a variety of fields, above all organizational studies.” Cristofaro, Matteo, *Organizational sensemaking: A systematic review and a co-evolutionary model*, 40(3) EUROPEAN MGMT. J. 393 (June 2022) (attached as Ex. 6 to Ewald Cert.).).

²⁸ (Rep. ¶¶ 44, 47.)

understandings over time to codify a “map” of internalized knowledge.²⁹ She refined her research as it progressed, consistent with contemporary theory on qualitative data analysis.³⁰

Dr. Sutcliffe’s report also details the data analysis she and her team performed, which included checks to reconcile disparate views among the team regarding interpretations of the materials reviewed.³¹ Dr. Sutcliffe and her team reviewed a large volume of materials, including J&J’s productions in litigation, deposition and trial transcripts, publicly available materials, and interviews that she conducted, and academic literature that was “consistent with, inconsistent with, and neutral to [her] hypotheses.”³² Contrary to Plaintiffs’ claim that Dr. Sutcliffe “relied on J&J’s attorneys to feed her documents,” Br. at 5, after counsel provided her 600 documents as an “initial data sample” on topics she had requested, Dr. Sutcliffe “requested and received access to J&J’s full global production record” in litigation matters over

²⁹ (Id. ¶¶ 43, 52-57.)

³⁰ (Id. ¶¶ 52-57.) Plaintiffs suggest that the iterative nature of Dr. Sutcliffe’s analysis is somehow improper, Br. at 5-6, but such iteration is a feature of qualitative research. (See, e.g., Rep. ¶¶ 55 n.45 and 62 nn.54-55 (citing support in Miles and Huberman that a researcher should “[e]xpect to do several iterations” and to work “in progressive ‘waves’ as the study progresses,” respectively); see also id. ¶ 72 n.63 (citing Miles and Huberman at 91 (“the researcher typically moves through a series of analysis episodes that then condense more and more data into a more and more coherent understanding of what, how, and why.”)).

³¹ (Id. ¶¶ 67-72.)

³² (Id. ¶¶ 64-66.)

J&J's talc products and her team performed their own queries to identify documents for analysis.³³ She used a "theory-based sampling strategy" to purposefully assess the voluminous materials.³⁴

The fact that Dr. Sutcliffe did not employ "quantitative methods" or use "pre-determined scoring metrics or rubrics" does not, as Plaintiffs argue, make Dr. Sutcliffe's methodology not "testable or repeatable," Br. at 6, nor is it grounds for exclusion. *See Bowers v. Nat'l Collegiate Athletic Ass'n*, 564 F. Supp. 2d 322, 361 (D.N.J. 2008) (admitting opinions regarding flaws in the NCAA's eligibility criteria based on social scientist's review of data, documents, testimony, literature in the field, and his own knowledge and experience; "This is not cutting-edge science, but is instead a conventional social science approach that courts have routinely admitted as methodologically reliable."). *See also United States v. Simmons*, 470 F.3d 1115, 1123 (5th Cir. 2006) (upholding the district courts' authority to admit testimony regarding "areas of expertise, such as the 'social sciences in which the research, theories and opinions cannot have the exactness of hard science methodologies'"') (citation omitted)); *Louis Vuitton Malletier S.A. v. Sunny Merch. Corp.*, 97 F. Supp. 3d 485, 507 (S.D.N.Y. 2015) ("[T]hat an analysis may be qualitative does not mean

³³ (*Id.* ¶¶ 59-62.)

³⁴ (*Id.* ¶ 60.)

that it is unreliable for the purposes of Daubert.”). Dr. Sutcliffe used methods and frameworks that are accepted in her field to ensure the reliability of her work.³⁵

B. Dr. Sutcliffe did not ignore significant evidence on talc and ovarian cancer after 1980.

Plaintiffs blatantly mischaracterize Dr. Sutcliffe’s opinions to argue that they somehow are cabined to the 1970s. They write: “she opined that the sole period of potential safety issues relating to talc safety—what she called ‘disruptive ambiguity’—*ended* in the 1970s” and that she did not conduct any research or formulate opinions on “what occurred inside J&J in the 1980s, 1990s, 2000s, and 2010s” including regarding “the link between talc and ovarian cancer.” Br. at 2. Plaintiffs’ claims are demonstrably false and easily overcome by simply reading her report.

1. Plaintiffs misrepresent Dr. Sutcliffe’s opinions as focusing “solely” on questions around asbestos in talc in the 1970s.

Plaintiffs misrepresent statements in Dr. Sutcliffe’s report and deposition testimony to falsely describe her opinions. For example, they wrote that Dr. Sutcliffe “is *unequivocal* on this, that J&J’s ‘confusion . . . over asbestos in talc’ ended in ‘the 1970s,’” citing paragraph 109 of her report. Dr. Sutcliffe did not say, in fact, that confusion over asbestos ended in the 1970s. The full paragraph they cited says:

³⁵ (*Id.* ¶¶ 49-50.) See Miles and Huberman at 277-280 (detailing standards for assessing the quality or reliability of qualitative work).

During the confusion of the 1970s over asbestos in talc, J&J and others faced regulatory uncertainty that threatened, often unintentionally, to prevent talc from ever being used as an ingredient. J&J responded by publicly engaging with the relevant authority and demonstrating the unintended consequences of the proposed regulations.³⁶

Similarly, Plaintiffs misleadingly write that Dr. Sutcliffe opined, “J&J’s sole period of ‘disruptive ambiguity’ was in ‘the early 1970s,’” Br. at 7 (citing paragraphs 188³⁷ and 190³⁸ in her report). *See also id.* at 14 (“According to Dr. Sutcliffe, the only period where there were genuine questions relating to asbestos in talc was in the 1970s”). Nowhere did Dr. Sutcliffe use the words “sole” or “only” to describe the disruptive ambiguity that occurred in the 1970s.

³⁶ (Rep. ¶ 109.)

³⁷ Paragraph 188 of Dr. Sutcliffe’s report actually says:

J&J continued to attend to signals about the safety of baby powder, even after much of the disruptive ambiguity from the early 1970s had been resolved and its new “map” had been codified. The organization applied its “map” and its sensemaking capabilities **to quickly investigate and respond to new allegations and ambiguities that arose**, and regularly updated its “map” based on a continuing engagement with regulators and the scientific community.

(emphasis added).)

³⁸ Paragraph 190 says:

Since the disruptive ambiguity of the early 1970s, J&J has devoted significant resources and attention to developing, validating, disseminating, and challenging a “map” that codifies the existing scientific knowledge regarding the detection of asbestos in talc and the safety of talc.”

(emphasis added).)

As Dr. Sutcliffe explains, sensemaking is typically triggered by “disruptive ambiguity.”³⁹ Disruptive ambiguity describes a period of uncertainty where “there are multiple and conflicting interpretations of what’s going on.”⁴⁰ Dr. Sutcliffe explains that the “wide sharing, testing, and revising of the ‘map’ [of internalized knowledge] continues even after the initial disruptive ambiguity is resolved, particularly where new information enters the environment.”⁴¹

Dr. Sutcliffe’s report describes an *initial* period of “disruptive ambiguity” in 1971-1973 when “confusion regarding definitions of asbestos, and how to identify asbestos in talc, collided with a lack of regulatory testing standards and evolving science on these questions.”⁴² That period was characterized by a confused flurry of activity among those in the talc industry, regulators, scientists, and the press following nascent allegations of asbestos contamination of consumer cosmetic products, testing that later proved to be incorrect or suspect, and conflicting regulatory definitions of asbestos.⁴³ After J&J’s engagement with industry and regulatory stakeholders in the early 1970s, the second half of the 1970’s saw J&J codify its “map” and take “actions to formalize its robust sensemaking practices for

³⁹ (*Id.* ¶ 43, nn.25-27.)

⁴⁰ (Sutcliffe Dep. 107:17-108:2.)

⁴¹ (Rep. ¶ 43.)

⁴² (*Id.* ¶ 90.)

⁴³ (*See id.* ¶¶ 90-122.)

continued use.”⁴⁴ During that time, improved methods led to a reassessment of earlier concerns about the presence of asbestos in cosmetic talc, and J&J continued to address new information concerning the safety of cosmetic talc to improve its understanding and knowledge.⁴⁵ By the end of the 1970s, J&J’s “map” was fairly stable.⁴⁶

Despite that relative stability, Plaintiffs are incorrect that “Dr. Sutcliffe’s own testimony is that J&J gave up on ‘sensemaking’ after the 1970s ‘disruptive ambiguity’ ended,” Br. at 35, or that, “[a]s she documents, J&J’s ‘map’ of information was fixed by the 1970s,” Br. at 14 (citing Rep. ¶ 162—which actually says J&J “continue[d] to engage with regulators and the scientific community to regularly update its ‘map.’”). And they are just plain wrong that she did not review “post-1970s evidence.” Br. at 16.

Rather, Dr. Sutcliffe opines that after active engagement with regulators and scientists during the initial disruptive period, J&J reached a foundational understanding regarding the safety of its talc products; in the decades that followed (during which disagreement over the methods and terminology around talc

⁴⁴ (Id. ¶¶ 123-124.)

⁴⁵ (Id. ¶ 138.)

⁴⁶ (See *id.* ¶ 166 (“none of the regulatory standards have been revised in ways that disrupt J&J’s ‘map’ of the relevant scientific knowledge.”); *id.* ¶ 179 (“Decades later, the testing methods used by J&J remain consistent with those used by regulators currently.”).)

continued), J&J continued to actively engage with new allegations and scientific developments, “demonstrat[ing] an ongoing commitment to sensemaking and a willingness to revise its ‘map’ if any of these allegations were disconfirming of its current understanding.”⁴⁷ For example, Dr. Sutcliffe described J&J’s engagement and investigation into a 1991 paper regarding the purported testing of J&J talc, which again provided a new “map” that “resolved much of the earlier ambiguity” and strengthened J&J’s “ability to anticipate and respond to future disruptions.”⁴⁸ In addition, she analyzed J&J’s engagement with regulatory agencies including the National Toxicology Program (“NTP”), IARC, Health Canada, and the Interagency Working Group on Asbestos in Consumer Products throughout the 2000s.⁴⁹ She also described J&J’s response to the FDA’s October 2019 notification that a sample of J&J baby powder had tested positive for sub-trace levels of chrysotile, which she characterized as “another disruptive ambiguity to J&J’s ‘map’ of existing scientific knowledge.”⁵⁰

⁴⁷ (*Id.* ¶¶ 147, 160.)

⁴⁸ (*Id.* ¶¶ 159-161.)

⁴⁹ (*Id.* ¶¶ 166-179.)

⁵⁰ (*Id.* ¶¶ 180-185.)

2. Dr. Sutcliffe did not ignore evidence regarding an alleged link between ovarian cancer and talc.

Plaintiffs' criticisms regarding which studies and data Dr. Sutcliffe did or did not consider in her analysis are classic areas for cross-examination, not appropriate challenges to her reliability. And their claims that Dr. Sutcliffe ignored important "evidence" of an alleged link between talc and ovarian cancer are again belied by her report.

Plaintiffs point to three examples of "evidence" that they say Dr. Sutcliffe did not analyze or discuss in her report: Harlow et al., *Perineal Exposure to Talc and Ovarian Cancer Risk*, 80 OBSTETRICS & GYN J. 19 (July 1992) ("Harlow"); Cramer et al., *Genital Talc Exposure and Risk of Ovarian Cancer*, 81 INT'L J. CANCER 351 (1999) ("Cramer"); Mills et al., *Perineal Talc Exposure and Epithelial Ovarian Cancer Risk in the Central Valley of California*, 112 INT'L J. CANCER 458 (2004) ("Mills"). Br. at 17-21. Plaintiffs try to make the point that because Dr. Sutcliffe did not consider J&J's specific response to every individual paper during a fifty-year period, she could not perform a sensemaking methodology. But Plaintiffs again misunderstand or misconstrue Dr. Sutcliffe's methodology.

As Dr. Sutcliffe emphasized during her deposition when Plaintiffs repeatedly asked her how J&J reacted to a specific piece of evidence (including Harlow, Cramer, and Mills), Dr. Sutcliffe was focused on "J&J's pattern of actions over

time.”⁵¹ She did not perform “a systematic analysis of all the studies [she] looked through.”⁵² And that was by design. Dr. Sutcliffe is not an epidemiologist, and it would not have made sense for her to review every epidemiological study. She was not focused on “a single event” or a single paper in the fifty-year period she analyzed.⁵³ As an organizational scientist, she was focused on J&J’s “process of understanding and creating institutionalized knowledge over time.”⁵⁴ The numerous excerpts of her deposition testimony in Plaintiffs’ brief confirm only that: that Dr. Sutcliffe did not study each individual piece of evidence with which they confronted her. That fact does not render her methodology unreliable.

Additionally, Plaintiffs’ suggestion that Dr. Sutcliffe “admitted she had *no evidence* that J&J chose to take a retrospective look at the evolving science,” Br. at 21, misconstrues her testimony and is demonstrably false. Her report discusses numerous FDA statements, workshops, studies, and presentations that considered links between talc and ovarian cancer risk.⁵⁵ In fact, the materials reviewed by Dr. Sutcliffe and referenced in her report discuss the very studies that Plaintiffs accuse her of ignoring. For example, she discusses J&J employees’ participation in a 1994

⁵¹ (See, e.g., Sutcliffe Dep. 233:14-23.)

⁵² (*Id.* 238:14-239:2, 305:5-15.)

⁵³ (*Id.* 234:24-235:10, 250:4-11.)

⁵⁴ (*Id.* 107:11-16.)

⁵⁵ (Rep. ¶¶ 154-157, 163-165, 172.)

workshop co-sponsored by the FDA and the International Society of Regulatory Toxicology and Pharmacology where the possible association between talc exposure and ovarian cancer was discussed.⁵⁶ The source cited for that workshop describes how Dr. Harlow co-presented “a review of epidemiologic studies—including their own original studies—pertaining to perineal talc exposure and ovarian cancer risk. The studies reviewed . . . are detailed in the papers by Drs. Hartge and Harlow appearing in this issue of the journal.”⁵⁷ Similarly, the literature review that J&J provided to the NTP in 2002, which Dr. Sutcliffe described in paragraph 172 of her report, included both the Cramer and Harlow papers.⁵⁸

In addition, Dr. Sutcliffe’s report described J&J’s consideration of ample additional materials indicating a possible association between talc and ovarian cancer, starting with a study published in July 1982 by Dr. Daniel Cramer.⁵⁹ She then traced the development in research regarding that alleged link over the next several decades and included specific discussion of studies, assessments, or literature

⁵⁶ (Id. ¶ 157.)

⁵⁷ (Carr, C. Jelleff, The Int’l Soc. Of Reg. Toxicology & Pharmacology and USDA, *Talc: Consumer Uses and Health Perspectives*, Bethesda, Maryland, Jan. 31-Feb. 1, 1994, 21 REG. TOXICOLOGY AND PHARMACOLOGY 215 (Oct. 1, 1994) (DX9060) (attached as Ex. 7 to Ewald Cert.).)

⁵⁸ (Ltr. from the Cosmetic, Toiletry, and Fragrance Ass’n to the Director of the NTP (March 18, 2002) (JNJTALC000109268) at 5-6 (listing the Cramer and Harlow studies among the publications) (attached as Ex. 8 to Ewald Cert.).)

⁵⁹ (Rep. ¶¶ 153-154.)

reviews conducted externally or by J&J in at least 1983, 1985, 1986, 1989, 1994, 1997, 2004, 2008, and 2020.⁶⁰ The examples she provided included a March 2020 briefing document developed by J&J; she noted that

[w]ith respect to research related to ovarian cancer, J&J conducted a ‘systematic review of the published literature [. . .] to identify epidemiologic studies of talc use and ovarian cancer in humans,’ and summarized 47 relevant studies.[] J&J concluded from this review that ‘[o]n balance, given the more than 47 years of research available on talc use and ovarian cancer, comprehensive consideration of all the available data supports that talc does not cause ovarian cancer.’⁶¹

Plaintiffs selectively ignore this evidence in order to construct their meritless argument.⁶²

⁶⁰ *(Id.* ¶¶ 154-157, 164-165, 172.)

⁶¹ *(Id.* ¶ 157 nn.322-324 (citing Johnson & Johnson Consumer, Inc., *Johnson’s Baby Talcum Powder: A Comprehensive Review* (Marcy 17, 2020) (JNJTALC001465273) at 286, 370-371, and 495) (attached as Ex. 9 to Ewald Cert.).)

⁶² Plaintiffs add as an aside that Dr. Sutcliffe “ignored her own rules for corporate behavior” from her testimony in “the *Deepwater Horizon/BP* oil spill case” because there “she opined on the need for *clear* policies and procedures ‘that reflect a commitment to safety.’” Br. at 28-29. As Dr. Sutcliffe explained in her deposition, unlike in *Deepwater*, she was not hired to analyze J&J’s “safety culture.” Sutcliffe Dep. 175:10-176:1. And Dr. Sutcliffe’s opinion in that case was not, as Plaintiffs write, “struck on *Daubert* grounds.” Br. at 28. Rather, as Dr. Sutcliffe also explained during her deposition, Sutcliffe Dep. 72:19-74:1, but Plaintiffs ignore in their motion, the Court in a footnote struck her rebuttal report as unnecessary due to the exclusion of an *opposing expert* that she had been rebutting. *In re: Oil Spill by the Oil Rig “Deepwater Horizon” in the Gulf of Mexico, on April 20, 2010*, No. 10-4536, 2014 WL 7185438, at *3 n.7 (E.D. La. Dec. 16, 2014).

III. Dr. Sutcliffe's opinions fit the facts of the litigation.

The Third Circuit has explained that “admissibility depends in part on ‘the proffered connection between the scientific research or test result to be presented and particular disputed factual issues in the case.’” *In re Paoli*, 35 F.3d at 743 (quoting *United States v. Downing*, 753 F.2d 1224, 1237 (3d Cir. 1985)). For expert testimony to “fit” the case, “it simply must bear enough of a relation to the facts and issues of the case to be of aid to the jury in resolving a dispute of fact.” *Dzielak v. Whirlpool Corp.*, No. 2:12-0089, 2017 WL 1034197 at *13 (D.N.J. March 17, 2017). Plaintiffs argue that Dr. Sutcliffe’s opinions do not fit the issues in this case for two reasons, neither of which supports her exclusion.

First, Plaintiffs characterize this case as a product liability action whose questions are answerable by reference to “hard sciences”—with no place for opinions regarding organization science or organizational behavior. *See Br.* at 34-35. But Plaintiffs have put J&J’s organizational knowledge, motivations, and behavior at issue: Plaintiffs allege that J&J has known for decades that talc may pose health risks to consumers and that J&J ignored data regarding these risks and failed to adequately ensure the safety of its consumers. *See e.g.*, ECF No. 132, Pls.’ First Am. Compl. (March 16, 2017), ¶¶ 97-98, 107, 115, 128, 145, 149, 152-153, 189, 224-239.⁶³ For example, Plaintiffs’ negligence claim alleges that J&J “knew or should

⁶³ (See also Sutcliffe Dep. 16:21-17:7.)

have known that the PRODUCTS were unreasonably dangerous and defective,” *id.* ¶ 128; Plaintiffs’ fraud claim alleges that J&J “intentionally, willfully, and/or recklessly, with the intent to deceive, misrepresented and/or concealed material facts to consumers and users, including Plaintiffs . . . with knowledge of the falsity of their misrepresentations,” *id.* ¶ 152-53; and their fraudulent concealment claim alleges J&J “intentionally concealed safety issues with the PRODUCTS in order to induce consumers, including Plaintiffs, to purchase the PRODUCTS,” *id.* ¶ 189. Plaintiffs’ claim for punitive damages against J&J centers on what J&J knew and how it responded to that knowledge. *See id.* ¶¶ 224-239.

Dr. Sutcliffe opines that “[a]llegations that J&J ‘knew’ or hid the ‘truth’ about the alleged health risks associated with its baby powder are inconsistent with the record of J&J’s actions, decisions, and organizational commitment to the wellbeing of consumers.”⁶⁴ Her opinion that J&J’s actions “are consistent with behaviors I would expect to see in an organization that prioritizes consumer wellbeing” go directly to Plaintiffs’ allegations.

Second, Plaintiffs argue that her testimony does not fit the case because she focuses “solely” on the 1970s. For the reasons described *supra* II.B., there is no merit to this argument; Dr. Sutcliffe’s opinions pertain to J&J’s organizational behavior

⁶⁴ (Rep. ¶ 17.)

beginning with a period of disruptive ambiguity in the early 1970s and continuing through 2023.

CONCLUSION

For the reasons stated, this Court should permit Dr. Sutcliffe to testify regarding J&J's knowledge as an organization regarding allegations that its talc products are unsafe and whether its actions in response to that knowledge were consistent with an organizational commitment to the wellbeing of consumers.

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Respectfully submitted,

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CERTIFICATION OF SERVICE

I hereby certify that on August 22, 2024, a true and correct copy of the foregoing motion was filed electronically. Notice of this filing will be sent by operation of the Court's electronic filing system to all parties indicated on the electronic filing receipt. Parties may access this filing through the Court's system.

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